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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,513	03/27/2006	David R. Whitlock	D0460-7010US	3543
37462 7590 09/29/2009 LANDO & ANASTASI, LLP ONE MAIN STREET, SUITE 1100 CAMBRIDGE, MA 02142				
EXAMINER BARNHART, LORA ELIZABETH				
ART UNIT		PAPER NUMBER		
1651				
NOTIFICATION DATE		DELIVERY MODE		
09/29/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/573,513

Applicant(s)

WHITLOCK, DAVID R.

Examiner

Lora E. Barnhart

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendments

Applicant's amendments filed 7/29/09 to claims 1-3 have been entered. No claims have been canceled or added. Claims 1-14 remain pending in the current application, of which claims 1-8 are being considered on their merits. Claims 9-14 remain withdrawn from consideration at this time. References not included with this Office action can be found in a prior action. Any rejections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

Election/Restrictions

Applicant's election with traverse of the species "a subject who is at risk of developing obesity" and "*Nitrosomonas*" in the reply filed on 10/20/08 is still in effect over the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims (in light of the species election) are drawn to treating a subject at risk of developing obesity comprising identifying such a subject and applying ammonia-oxidizing bacteria (AOB) to the subject. At page 6, lines 14-17, the as-filed specification defines "to treat" as "to prevent or retard the onset of a disease or disorder as well as to retard or stop the progression of disease or disorder after its onset, or to reduce any symptoms commonly associated with the disorder, even if those symptoms do not reach the threshold for clinical disease." At page 6, lines 11-13, the as-filed specification limits the subject to a human or vertebrate animal. In some dependent claims, the AOB and amount to be applied is pointed out. In some dependent claims, the manner of application is further described.

Several aspects of the claims warrant discussion as it pertains to enablement. First, the definition of "treat" at page 6, lines 14-17, includes preventing obesity in a subject. Obesity is a persistent problem in the art. Johnson et al. (2006, *Journal of the American Dietetic Association* 106: 97-102), published years after the instant

application, teaches that obesity is a complex condition with many possible causes, including gender, race, socioeconomic condition, maternal contribution during gestation, learned behaviors, environmental factors, and age of onset of puberty (pages 97-100). Johnson concludes that even after the instant filing, additional research is necessary to identify ways to prevent obesity in all individuals, because there are so many different life periods at which intervention is necessary (page 100, column 2).

Methods for treatment of obesity were known in the art at the time of filing; these methods include special diets and weight reduction programs, e.g. exercise (Bojrab; U.S. Patent 6,641,808; at column 5, lines 34-56). Indeed, some probiotic bacteria have been shown to reduce body mass index when ingested orally (see Bojrab at column 9, lines 34-48). However, at the time of the invention, the art was silent as to the ability of any bacteria, administered in any way, to prevent obesity. Furthermore, there are no prior art teachings of topically applied bacteria of any kind preventing obesity. M.P.E.P. § 2164.03 reads, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The 'amount of guidance or direction' refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. **In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification**

would need more detail as to how to make and use the invention in order to be enabling. See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004)...In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required." As the above discussion illustrates, the ability of topically applied bacteria of any kind, including AOB, to prevent obesity was unpredictable at the time of the invention, so treatment of such diseases must be considered "nascent," and the amount of guidance required is relatively high.

When the state of the art is nascent, the examiner must turn to the guidance in the specification for guidance in carrying out the claimed invention. In this case, the working examples are limited to a single pilot experiment in which a composition allegedly comprising AOB was applied to the skin of a single individual (the inventor) and allowed to remain without being washed off for several years (see page 94, lines 15-18; and page 106, line 32). The working examples (see page 93, lines 25-33, and page 107, lines 1-12) do not clearly indicate that the composition applied in the working examples prevented obesity *per se*. It is noted that the inventor noted reduction in appetite and observed weight loss during the time the AOB was present (page 34, lines 20-24), but given the teachings of Johnson and Bojrab as to the complex nature of obesity, there is insufficient evidence to conclude that the application of AOB resulted in

prevention of obesity, especially since the specification does not clearly indicate that after the weight loss, the inventor was not obese; all that is discussed is a weight loss.

The claimed method requires applying AOB to the skin ("surface") of the subject. However, the specification does not clearly indicate that the working examples include such an application. The specification indicates (page 94, lines 15-16; and page 107, lines 1-4) that soil was obtained and cultured in ammonia-containing media, but the specification does not appear to include any evidence that the contents of the composition applied to the scalp and body of the experimental subject contained any particular bacterial strain, much less the specific strains recited in claim 2. The specification indicates that the "strain" used in the examples "does not utilize urea directly, and does not have a nitrate reductase" (page 95, lines 5-6). However, this information on its own is inadequate to establish that the bacteria allegedly present in the composition applied to the subject's body in the working examples are any particular strain of AOB or even that they are AOB.

Regarding the requirement in claim 3 that an "effective amount" of bacteria be applied to the skin ("surface") of a subject, the specification provides inadequate guidance to determine this amount. In *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993), the 1983 application disclosed a vaccine against the RNA tumor virus known as Prague Avian Sarcoma Virus, a member of the Rous Associated Virus family. Using functional language, Wright claimed a vaccine "comprising an immunologically effective amount" of a viral expression product. *Id.*, at 1559, 27 USPQ2d at 1511. Rejected claims covered all RNA viruses as well as avian RNA viruses. The examiner

provided a teaching that in 1988, a vaccine for another retrovirus (i.e., AIDS) remained an intractable problem. This evidence, along with evidence that the RNA viruses were a diverse and complicated genus, convinced the Federal Circuit that the invention was not enabled for either all retroviruses or even for avian retroviruses. The fact pattern is similar in this case, since Johnson and Bojrab indicate that preventing obesity is an unpredictable art, and the specification includes insufficient guidance for preventing obesity under any circumstances.

While a singular, narrow working embodiment cannot be a sole factor in determining enablement, its limited showing, in light of the unpredictable nature of the art and the lack of direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus, one of ordinary skill in the art would not have a reasonable expectation of success in using the claimed invention.

Response to Arguments

Applicant's reply includes speculation about the mechanism by which the claimed method purportedly works. Reply, page 5, paragraph 3, through page 6, paragraph 3. Applicant alleges that the skilled artisan would not have required undue experimentation at the time of the invention to determine the amount of bacteria effective to prevent obesity in a subject to which the bacteria are applied. Reply, page 5, last paragraph et seq. These arguments have been fully considered, but they are not persuasive.

All of the proffered arguments appear to be merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Attorney argument

is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See M.P.E.P. § 2129 and § 2144.03 for a discussion of admissions as prior art. Counsel's arguments cannot take the place of objective evidence. *In re Schulze*, 145 USPQ 716 (CCPA 1965); *In re Cole*, 140 USPQ 230 (CCPA 1964); and especially *In re Langer*, 183 USPQ 288 (CCPA 1974). See M.P.E.P. § 716.01(c) for examples of attorney statements that are not evidence and that must be supported by an appropriate affidavit or declaration.

Furthermore, the reply does not address by evidence or particular argument the examiner's point that the specification does not adequately establish that the composition applied in the working example contains AOB, much less the bacterial species in claim 2. Because this point has not been properly shown, applicant's general allegation that determining the effective amount to prevent obesity is groundless since applicant has not established that AOB are the active agent in the working example. Finally, as pointed out in the rejection, "weight loss" is not the same as "prevention of obesity." The fact that the inventor observed some weight loss allegedly due to the application of some composition does not establish that obesity was prevented, since there is no evidence that even after the weight loss, the inventor was not obese.

Applicant's statement that the skilled artisan could have identified the effective amount in claim 3 without undue experimentation could be interpreted as an admission that carrying out the claimed invention would have been obvious at the time of the invention, but the examiner declines to interpret the statement as such at this time.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While not elected species, there is a disconnect between the species "aging" and "autism" in the preamble of claim 1 and the "identifying" step of claim 1. There is no provision for identifying a subject who has developed or is at risk for aging or autism, but rather for identifying a subject who has developed or is at risk for "aging autism." Furthermore, the list of conditions in the "identifying" step appears to be incomplete in the absence of the word "and." Clarification is required.

Claim 1 requires "applying AOB to the subject to form a compound" and "treating the subject with the compound," but it is not clear whether the "treating" is an additional step or whether it is a natural, inherent effect of the applying step. Clarification is required.

The Markush group within the "applying" step is improper in the absence of a comma between "nitric oxide" and "a nitric oxide precursor." Clarification is required.

It is not clear which compounds constitute "a nitric oxide precursor" and which do not. Nitric oxide is a simple gas of the formula NO; it is not clear whether the term "nitric oxide precursor" is limited to nitrogen and oxygen or whether it should encompass any and all compounds that can, in some way, yield nitric oxide. Clarification is required.

Because claims 2-8 depend from indefinite claim 1 and do not clarify all of the points of confusion, it must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 3 requires applying bacteria "in an effective amount" to a surface of the subject being treated. The common phrase "an effective amount" may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an "effective amount of a compound of claim 1" without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the uses could be effected. See M.P.E.P. § 2173.05 (c) (III).

In this case, the specification does not provide any guidance for identifying a particular amount of any particular bacteria. At page 8, lines 3-14, the specification generally contemplates that any AOB can be used in the invention, but the working examples provide no guidance for identifying an effective amount of any of the recited bacteria for any purpose. At page 107, lines 1-12, of the as-filed specification, a process for producing "an enrichment culture of [AOB]" by culturing barnyard soil in ammonia-containing medium until the culture reached high levels of nitrite is disclosed. However, nowhere does the specification indicate that any of the bacteria recited in claim 2 are present in the composition applied at page 107, and the specification is also silent as to the amount of active agent applied. Given the enablement issues in this case (see above), it is not clear what amount of bacteria would constitute an "effective amount."

Because claims 4-8 depend from indefinite claim 3 and do not clarify the point of confusion, it must also be rejected under 35 U.S.C. 112, second paragraph.

Response to Arguments

Regarding the indefiniteness rejections of record, applicant alleges that claim 1 has been amended such that the preamble is commensurate in scope with the steps. See page 6, paragraph 5. However, as discussed above, the amendments to claim 1 introduce new sources of indefiniteness that require clarification.

Applicant alleges that determining the "effective amount" of claim 3 would not have required undue experimentation. Reply, page 7, paragraphs 1-3. However, these statements are not substantiated by factual evidence, especially given the fact that applicant has not conclusively established that AOB are applied in the composition of the working example and has not determined the amount of AOB applied, if any. Counsel's arguments cannot take the place of objective evidence.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-8 are/remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 3-8 of copending Application No. 10/332,933.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Instant claim 1 is drawn to a method of treating a subject who is at risk for obesity (i.e., any subject) by applying AOB to a subject; instant claim 3 requires applying the AOB such that they metabolize certain compounds. Claim 1 of the '933 application is drawn to a method of supplying nitric oxide to a subject (i.e., any subject) by applying AOB to the surface of the subject such that they metabolize certain compounds. Because the method steps are identical and the scope of the subject is identical (i.e., every individual) in both claim sets, the claims have identical scope. Instant claim 2 correlates with claim 4 of the '933 application. Instant claim 4 correlates with claim 3 of the '933 application. Instant claim 5 correlates with claim 5 of the '933 application. Instant claim 6 correlates with claim 6 of the '933 application. Instant claim 7 correlates with claim 7 of the '933 application. Instant claim 8 correlates with claim 8 of the '933 application.

Applicant alleges that the claims of the '933 application do not suggest using the instant steps to treat obesity. See reply, page 8, paragraph 3. These arguments have been fully considered, but they are not persuasive. Applicant's response does not address the fact that the steps in the '933 method are identical to those instantly claimed; since every individual is at risk for obesity, the instant method may be carried out on any individual. Applicant's comments regarding "treating obesity" are not germane to the elected species, "preventing obesity." Prevention and treatment are not the same.

Applicant's statement that "one skilled in the art would not have understood that ammonia oxidizing bacteria may be used to form nitric oxide to treat obesity" could be construed as an admission that the instantly claimed method is not enabled. The examiner declines to interpret this statement as such at this time, but repeated urging of this point may be used as an admission against applicant.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is (571)272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lora E Barnhart/
Primary Examiner, Art Unit 1651